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**PATENT**

Atty. Docket No.  
AR02817USACON

CN 27777

transmitted by facsimile to the Patent and Trademark Office, Fax Number \_\_\_\_\_

Date: May 13, 2004 By: Lois E. Miller

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s): Willaim VAN OSDOL et al.

Serial No.: 10/675,715

Filed: September 29, 2003

For: NOVEL FORMULATIONS FOR THE  
TRANSDERMAL ADMINISTRATION  
OF FENOLDOPAM

Group Art Unit: 1616

Examiner: to be assigned

**INFORMATION DISCLOSURE  
STATEMENT**

Honorable Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the

mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

☐ Statement in Accordance with §1.97(e) (attached); or

☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:

☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☒ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

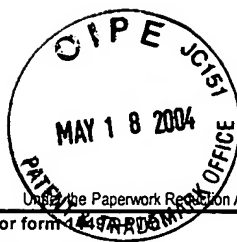
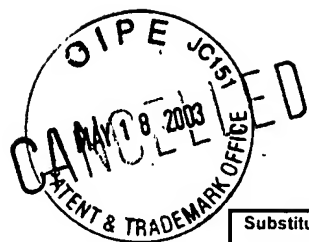
Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750.

Respectfully submitted,

  
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Attorney for Applicants

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Substitute for form 1449A

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 4

Application Number	10/675,715
Filing Date	September 29, 2003
First Named Inventor	William Van Osdol
Group Art Unit	1616
Examiner Name	To be assigned
Attorney Docket Number	AR02817USACON

### U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
		Number	Kind Code <sup>2</sup> (if known)			
	AA	6,238,693		LUTHER et al.	05-29-2001	
	AB	5,719,197		KANIOS et al.	02-17-1998	
	AC	5,686,097		TASKOVICH et al.	11-11-1997	
	AD	5,656,286		MIRANDA et al.	08-12-1997	
	AE	5,641,504		LEE et al.	06-24-1997	
	AF	5,635,203		GALE et al.	06-03-1997	
	AG	5,629,019		LEE et al.	05-13-1997	
	AH	5,451,407		CORMIER et al.	09-19-1995	
	AI	5,378,730		LEE et al.	01-03-1995	
	AJ	5,342,623		ENSCORE et al.	08-30-1994	
	AK	5,314,694		GALE et al.	05-24-1994	
	AL	5,304,379	B1	CORMIER et al.	04-19-1994	
	AM	5,284,660		LEE et al.	02-08-1994	
	AN	5,160,741		CORMIER et al.	11-03-1992	
	AO	5,149,539		LEDGER et al.	09-22-1992	
	AP	5,141,750		LEE et al.	08-25-1992	
	AQ	5,130,139		CORMIER et al.	07-14-1992	
	AR	5,122,382		GALE et al.	06-16-1992	
	AS	5,120,145		KAWAHARA	06-09-1992	
	AT	5,071,656		LEE et al.	12-10-1991	
	AU	5,049,387		AMKRAUT	09-17-1991	
	AV	5,028,431		FRANZ et al.	07-02-1991	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A-PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 4

<i>Application Number</i>	10/675,715
<i>Filing Date</i>	September 29, 2003
<i>First Named Inventor</i>	William Van Osdol
<i>Group Art Unit</i>	1616
<i>Examiner Name</i>	To be assigned
<i>Attorney Docket Number</i>	AR02817USACON

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		Number	Kind Code <sup>2</sup> (if known)			
	AW	5,004,610		OSBOURNE et al.	04-02-1991	
	AX	5,000,956	B1	AMKRAUT et al.	03-19-1991	
	AY	4,943,435		BAKER et al.	07-24-1990	
	AZ	4,938,759		ENSCORE et al.	07-03-1990	
	BA	4,917,895		LEE et al.	04-17-1990	
	BB	4,908,027		ENSCORE et al.	03-13-1990	
	BC	4,904,475		GALE et al.	02-27-1990	
	BD	4,900,555		CHENG et al.	02-13-1990	
	BE	4,888,354		CHANG et al.	12-19-1989	
	BF	4,865,848		CHENG et al.	09-12-1989	
	BG	4,863,738		TASKOVICH	09-05-1989	
	BH	4,849,226		GALE et al.	07-18-1989	
	BI	4,816,258		NEDBERGE et al.	03-28-1989	
	BJ	4,788,062		GALE et al.	11-29-1988	
	BK	4,781,924		LEE et al.	11-01-1988	
	BL	4,764,379		SANDERS et al.	08-16-1988	
	BM	4,756,710		BONDI et al.	07-12-1988	
	BN	4,746,515		CHENG et al.	05-24-1988	
	BO	4,725,272		GALE	02-16-1988	
	BP	4,705,862		LABAW et al.	11-10-1987	
	BQ	4,704,282		CAMPBELL et al.	11-03-1987	
	BR	4,698,062		GALE et al.	10-06-1987	
	BS	4,645,502		GALE et al.	02-24-1987	

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Sheet 2 of 4

<i>Application Number</i>	10/675,715
<i>Filing Date</i>	September 29, 2003
<i>First Named Inventor</i>	William Van Osdol
<i>Group Art Unit</i>	1616
<i>Examiner Name</i>	To be assigned
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		Number	Kind Code <sup>2</sup> (if known)			
	BT	4,588,580		GALE et al.	05-13-1986	
	BU	4,573,995		CHENG et al.	03-04-1986	
	BV	4,568,343		LEEPER et al.	02-04-1986	
	BW	4,559,222		ENSCORE et al.	12-17-1985	
	BX	4,552,872		COOPER et al.	11-12-1985	
	BY	4,435,180		LEEPER	03-06-1984	
	BZ	4,379,454		CAMPBELL et al.	04-12-1983	
	CA	4,321,195		WEINSTOCK	03-23-1982	
	CB	4,314,557		CHANRASEKARAN	02-09-1982	
	CC	4,286,592		CHANRASEKARAN	09-01-1981	
	CD	4,201,211		CHANRASEKARAN et al.	05-06-1980	
	CE	4,197,297		WEINSTOCK	04-08-1980	
	CF	4,144,317		HIGUCHI	03-13-1979	
	CG	4,031,894		URQUHART et al.	06-28-1977	
	CH	3,797,494		ZAFFARONI	03-19-1974	
	CI	3,731,683		ZAFFARONI	05-08-1973	
	CJ	3,598,122		ZAFFARONI	11-23-1982	
	CK	3,589,123		ZAFFARONI	08-10-1971	

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<b>Examiner Name</b>	To be assigned
<b>Attorney Docket Number</b>	AR02817USACON

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	KindCode <sup>5</sup>				
	CL	WO	99/55341		Elan Pharmaceuticals, Inc.	11-04-1999		
	CM	WO	99/15210		Noven Pharmaceuticals, Inc.	04-01-1999		
	CN	WO	96/40259		ALZA Corporation	12-19-1996		
	CO	WO	96/37231		ALZA Corporation	11-28-1996		
	CP	WO	95/09006		ALZA Corporation	04-06-1995		
	CQ	WO	95/01167		ALZA Corporation	01-12-1995		
	CR	WO	91/16041		SmithKline & French Labs Ltd.	10-31-1991		

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published	T <sup>2</sup>
	CS	Nancy L. ALLISON et al., <u>Clin Pharmacol Ther</u> , 41:282-288, March 1987. "The effect of fenoldopam, a dopaminergic agonist, on renal hemodynamics"	
	CT	K.F. BODMANN et al., <u>Clinical Investigator</u> , 72:60-64, 1993. "Hemodynamic profile of intravenous fenoldopam in patients with hypertensive crisis"	
	CU	Gary W. CLEARY, <u>Topical Drug Bioavailability, Bioequivalence, and Penetration</u> , Chapter 2, pp. 17-68, Plenum Press, 1993. "Transdermal delivery Systems: A Medical Rationale"	
	CV	Terry L. HOLCSLAW et al., <u>American Journal of Hypertension</u> , 3(6) Part 2:120S-125S, 1990. "Clinical Experience with Intravenous Fenoldopam"	
	CW	Diane K. JORKASKY et al., <u>American Journal of Kidney Diseases</u> , XIX(6):567-572, June 1992. "Fenoldopam Reverses Cyclosporine-Induced Renal Vasoconstriction in Kidney Transplant Recipients"	
	CX	Victoria.M. KNEPP et al, <u>CRC Critical Reviews and Drug Carrier Systems</u> , 4(1):13-37, (1987). "Transdermal Drug Delivery: Problems and Possibilities"	
	CY	Andrew J. NICHOLS et al., <u>American Journal of Hypertension</u> , 3(6) Part 2:117S-119S, 1990. "The Pharmacology of Fenoldopam"	
	CZ	H.P. SCHUSTER, et al. <u>Intensivmed</u> , 28:348-355, 1991 "Fenoldopam improves renal dysfunction secondary to ventilation with PEEP"	
	DA	Philip W. WERTZ et al, <u>Advanced Drug Delivery Reviews</u> , 12:1-12, 1993. "Regional variation in the structure and permeability of oral mucosa and skin"	

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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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